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| 10/528,748 | 03/13/2006 | Claas Junghans | JUNGHANS | 9385 |

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| EXAMINER |
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LEAVITT, MARIA GOMEZ

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| ART UNIT | PAPER NUMBER |
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1633

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| NOTIFICATION DATE | DELIVERY MODE |
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01/04/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@FEIEREISENLLC.COM

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| Office Action Summary | Application No. 10/528,748 | Applicant(s) JUNGHANS ET AL. | |
| | Examiner MARIA LEAVITT | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-11,22,23,25,27 and 29-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-11,22,23,25,27,29,31 and 33 is/are allowed.
- 6) ☒ Claim(s) 36-39 is/are rejected.
- 7) ☒ Claim(s) 30,32,34-38 and 40 is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Status of claims. Claims 8-11, 22, 23, 25, 27, 29-40 are pending. Claims 12, 13, 15-20, 24, 26, and 28 have been cancelled and claims 39 and 40 have been added by Applicants' amendment filed on 10-02-2009. Claims 25, 27, 31-34 and 37-38 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Amended claim 22 is allowable. Because the genus claim is allowable as originally claimed, other species will be rejoined for search and examination, i.e. SEQ ID NOS: 7 and 8. As such, claims 25, 27, 31-34 and 37-38 are rejoined for examination. New claims 39 and 40 read on the elected invention.
3. Therefore, claims 8-11, 22, 23, 25, 27, 29-40 are currently under examination to which the following grounds of rejection are applicable.

Withdrawn Objections in response to Applicants' arguments or amendments

Numbering of Claims

In view of Applicants' renumbering of claims 38 and 39 as claims 37 and 38 objection to claims 38 and 39 under 37 CFR 1.126 has been withdrawn.

Claim Rejections - 35 USC § 102

In view of applicants amendment of claim 36, rejection of claims 23 and 36 under 35 USC. 102(b) as being anticipated by Paoletti E (WO9215672, Date of publication 17-Sep-1992;

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see Result 5, SCORE Search Results Details for Application 10528748 and Search Result 20080609_130757_us-10-528-748-5.rng) as evidenced by Kennell (*Progr Nucleic Acid Res. Mol. Biol.* 11: 259-301, 1971, at the paragraph bridging pages 260-261) has been withdrawn.

In view of the withdrawn rejection, applicant's arguments are rendered moot.

Objections/Rejections maintained in response to Applicants' arguments or amendments

Notice To Comply with Sequence Rules For Patent Applications Containing nucleotide Sequence And/Or Amino acid Sequence Disclosures

Applicants' filing of a Computer readable form on 10-27-2009 to specifically list and identify the claimed peptide sequence comprising PKKKRKV as SEQ ID NO: 41 is acknowledged. However, in response to Applicants' filing of a sequence listing in computer readable form and in printing on 10-27-2009, objection to the specification remains for the following reasons: The Biotechnology system branch of the Scientific and Technical Information Center (STIC) of USPTO experienced a problem when processing the computer readable form for the Application Serial Number 10/528,748 (please, CFR document printed by STIC). Search of amino acids of SEQ ID No. 41 is neces8-11, sary for examination of claims 11.

For compliance with the sequence rules, it is necessary to include the sequence in the "Sequence Listing" as required by 37 C.F.R. 1.821(c) and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.821(a), must be set forth in the "Sequence Listing". (see MPEP 2422.03).

The following items are required:

2. a nucleotide and/or amino acid sequence listing in computer readable form and

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3. a statement that the information recorded in computer readable form is identical to the written sequence listing are required.

To be fully responsible, Applicant is required to comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specification objection

The Specification remains objected as failing to with the requirements of 37 CFR 1.821

(d), which states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

The specification and claims disclose amino acid and nucleotides sequences which are described or named with improper identifiers, for example, at page 18, on lines 5, a sequence identifier for sequence ID NO:5 should be abbreviated as **SEQ ID NO:5** and not Seq.ID5.

Applicants are required to amend the specification to identify the sequences with the corresponding SEQ ID NOS. and to ensure that each SEQ ID NO: is provided in the initial or substitute CRF and paper copy sequence listing. Additionally, for completeness, Applicants are advised to review the entire disclosure for compliance with 37 CFR §1.821(d).

Claim Objection

Claims 30, 32 and 34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claims 29, 31 and 33. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, SEQ ID NOS: 5, 7

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and 8 inherently provide protection from Feline Leucosis virus infection”, as recited in claims 30, 32 and 34 when expressed in cat cells. The examiner suggest inserting the clause “wherein the expression of the construct in cat cells provides protection from Feline Leucosis virus infection” following the phrases, “set forth in SEQ ID NO:5”, “ set forth in SEQ ID NO:7” and “set forth in SEQ ID NO:8” as recited in claims 29, 31 and 33, respectively.

Claim 35 is objected to because of the following informality: the indefinite article “an” is necessary before the term “animal” in line 4. Appropriate correction is requested.

Claim 36 is objected to because of the following informality: punctuation with a colon (:) is suggested after the abbreviated term “NOS” ” in line 3. Appropriate correction is requested.

Claim 37 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, SEQ ID NO: 7 is a mutagenized “env” gene (gp85) sequence of 1929 nucleotides in length. Claim 37 is a product by process PCR of such sequences from SEQ ID NO: 7. Accordingly, any PCR fragments from any env” gene (gp85) sequence portion of SEQ ID NO: 7 would anticipate claim 37, but not the parent claim, as claim 25 requires the entire sequence, i.e., prior art could anticipate the dependent claim but not the parent.

Likewise, claim 38 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, SEQ ID NO: 8 is a mutagenized “env”

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gene (gp70) sequence of 1440 nucleotides in length. Claim 28 is a product by process PCR of such sequences from SEQ ID NO: 8. Accordingly, any PCR fragments from any “env” gene (gp70) sequence portion of SEQ ID NO: 8 would anticipate claim 38, but not the parent claim, as claim 27 requires the entire sequence, i.e., prior art could anticipate the dependent claim but not the parent.

Additionally, new claim 40 which depends on claim 8 which depends on claims 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, new claim 40 recites, “comprising: a promoter sequence operable in Felidae and at least one Feline Leucosis mutated virus nucleotide sequence, wherein the mutated nucleic acid comprises the sequence that encodes a protein set forth in one of the group consisting of SEQ ID NO: 5, SEQ ID NO: 7 and SEQ ID NO: 8; and a termination sequence”. However the DNA expression construct of claim 8 already comprises at least one protein from the group consisting of SEQ ID NO: 5, SEQ ID NO: 7 and SEQ ID NO: 8. Thus, new claim 40 is of the same scope that parent claim 8 and does not further limit the breadth of claim 8.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim remain rejected 36 an claims 37, 38 and 39 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

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distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection necessitated by amendment of the claims in the response filed 10/02/2009.**

Claim 36 is indefinite in the reciting “wherein the gag coding sequence” in line 2. There is no antecedent basis for the gag coding sequence in the claim or the claims from which it depends.

Similarly, claim 37 is indefinite in the reciting “wherein the env-gp85 coding sequence” in line 2. There is no antecedent basis for the env-gp85 coding sequence in the claim or the claims from which it depends.

Claim 38 is indefinite in the reciting “wherein the env-gp70 coding sequence” in line 2. There is no antecedent basis for the env-gp70 coding sequence in the claim or the claims from which it depends. Therefore, the metes and bounds of “the env-gp70 coding sequence” are indefinite.

New claim 39 is vague and indefinite in its recitation of the phrase "use as a vaccine" in that the metes and bounds of the term “use as a vaccine” are unclear. It is unclear whether new claim 39 encompasses a method or a product claim. Applicant appears to be attempting to claim both a composition and a use thereof, which is not statutory. The claims should be redrafted such that they particularly point out the components and, where necessary, the absolute amounts thereof within the composition. As such, the metes and bounds of the claims cannot be determined.

Response to Applicants’ remarks as they apply to rejection to claim 36 under 35 USC § 112- Second Paragraph

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At page 9 of the remarks filed on 10-02-2009, Applicants essentially argue that “the gag sequence” refers to SEQ ID NO: 5 and is therefore considered proper with definitive article.

With respect to applicants' argument that, " the gag sequence refers to SEQ ID NO: 5 " is not found persuasive because it is noted that the features upon which applicant relies, i.e., the gag sequence, is not recited in the rejected claim 36. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, claim 23 does not recite “the gag coding sequence” taught in the specification. Hence the argument is not persuasive as they argue limitations that are not present in claims.

Conclusion

Claims 36, 37, 38 and 39 are rejected.

Claims 30, 32, 34-38 and 40 are objected

Claims 8-11, 22, 23, 25, 27, 29, 31 and 33 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maria Leavitt/

Maria Leavitt
Primary Examiner, Art Unit 1633